

## ***Policies and Statements on Dual Use Research***

*Prepared by NIH Office of Biotechnology Activities Staff (June 2008)*

### **Samples of Existing Journal Policies on Dual Use Research**

#### ***ASM JOURNALS<sup>1</sup>***

##### **POLICY GUIDELINES OF THE PUBLICATIONS BOARD OF THE ASM IN THE HANDLING OF MANUSCRIPTS DEALING WITH MICROBIOLOGICAL SENSITIVE ISSUES**

###### *Statement of the ASM Council Policy Committee*

“The Council Policy Committee of the American Society for Microbiology affirms the long-standing position of the Society that microbiologists will work for the proper and beneficent application of science and will call to the attention of the public or the appropriate authorities misuses of microbiology or of information derived from microbiology. ASM members are obligated to discourage any use of microbiology contrary to the welfare of humankind, including the use of microbes as biological weapons. Bioterrorism violates the fundamental principles expressed in the Code of Ethics of the Society and is abhorrent to the ASM and its members”

###### *ASM Publications Board Policy and Procedures*

As described in the Council Policy Committee resolution, the ASM recognizes that there are valid concerns regarding the publication of information in scientific journals that could be put to inappropriate use. Members of the ASM Publications Board will evaluate the rare manuscript that might raise such issues during the review process. Research articles must contain sufficient detail to permit the work to be repeated by others. By publishing in an ASM journal, the authors agree that any plasmids, viruses, and living materials, such as microbial strains and cell lines newly described in the article, are available from a national collection or will be made available in a timely fashion and at reasonable cost to members of the scientific community for non-commercial purposes. It is also expected that newly assigned GenBank/EMBL/DDBJ accession numbers for nucleotide and/or amino acid sequence data will be included in the original manuscript or be inserted when the manuscript is modified, and that the data will be released to the public by the time the manuscript is published. Supply of these materials must be in accordance with laws and regulations governing the shipment, transfer, possession, and use of biological materials and must be for legitimate, bona fide, research needs. Please refer to the appropriate websites about these laws and regulations which can be found from the ASM website ([Laws and Regulations Governing the Shipment, Transfer, Possession and Use of Biological Materials.](#))

In order for the Publications Board to comply with the policy statement, ALL Editors of ALL ASM journals should take the following course of action:

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<sup>1</sup> Available online: [http://journals.asm.org/misc/Pathogens\\_and\\_Toxins.shtml](http://journals.asm.org/misc/Pathogens_and_Toxins.shtml)

1. Ask ALL reviewers to advise the Editor, by use of the Confidential Comments section of the review form and the appropriate check-off box when it becomes available, if, in their opinion, the manuscript under review describes misuses of microbiology or of information derived from microbiology.
2. The Editor should serve as an initial screen with regards this matter and may be the point of contact with the author(s).
3. If a reviewer brings such a matter to an Editor's attention, the Editor should provide copies of the manuscript to the Editor in Chief, the Chair of the Publications Board, and the Director of Journals. The Editor should hold the manuscript and all reviews until contacted by the Editor in Chief.
4. The Editor in Chief will contact the Chair of the Publications Board, and together they may render a decision or, at their discretion, consult the entire Publication Board to determine whether to resume the review process or to decline the manuscript and return it to the author.

### ***NATIONAL RESEARCH COUNCIL CANADA RESEARCH PRESS<sup>2</sup>***

Publishing Policy: Editorial and Ethical Responsibilities

#### **Security**

Any paper or monograph submitted for publication that raises concern because of the potential misuse of methods, technologies or agents reported for nefarious purposes may be subject to editorial review to determine the risks and benefits to the scientific community and the public at large that may result from publication. Such review will be taken into account by the Editor(s) in making a final decision concerning publication.

### ***NATURE<sup>3</sup>***

#### **Nature journal's policy on biosecurity**

Nature journal editors may seek advice about submitted papers not only from technical reviewers but also on any aspect of a paper that raises concerns. These may include, for example, ethical issues or issues of data or materials access. Very occasionally, concerns may also relate to the implications to society of publishing a paper, including threats to security. In such circumstances, advice will usually be sought simultaneously with the technical peer-review process. As in all publishing decisions, the ultimate decision whether to publish is the responsibility of the editor of the Nature journal concerned.

The threat posed by bioweapons raises the unusual need to assess the balance of risk and benefit in publication. Editors are not necessarily well qualified to make such judgments unassisted, and so we reserve the right to take expert advice in cases where we believe that concerns may arise. We recognize the widespread view that openness in science helps to alert society to potential threats and to defend against them, and we anticipate that only very rarely (if at all) will the risks be perceived as outweighing the benefits of publishing a paper that has otherwise been deemed

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<sup>2</sup> Available online: <http://pubs.nrc-cnrc.gc.ca/eng/policy/index.html#security>

<sup>3</sup> Available online: [http://www.nature.com/authors/editorial\\_policies/biosecurity.html](http://www.nature.com/authors/editorial_policies/biosecurity.html)

appropriate for a Nature journal. Nevertheless, we think it is appropriate to consider such risks and to have a formal policy for dealing with them if need arises.

The editorial staff of Nature journals maintains a network of advisors on biosecurity issues. All concerns on that score, including the commissioning of external advice, will be shared within an editorial monitoring group consisting of the Editor-in-Chief of Nature publications, the Executive Editor of the Nature research journals, the Chief Biological Sciences Editor of Nature, and the chief editor of the journal concerned.

Once a decision has been reached, authors will be informed if biosecurity advice has informed that decision. Please see the [joint statement by journal editors](#).

Nature journal editorials providing more details on biosecurity policies and publishing issues:

*Nature Medicine*: [Freedom of information](#)

*Nature*: [Statement on the consideration of biodefence and biosecurity](#)

*Nature Immunology*: [Dealing with potential dangers](#)

*Nature Methods*: [The challenge of responsible methods](#)

*Nature Immunology*: [Biosecurity with 'bio-sense'](#)

*Nature*: [Rules of engagement](#)

*Nature*: [Risks and benefits of dual-use research](#)

*Nature*: [Network of concern](#)

*Nature*: [Towards better biosecurity](#)

(Extract from *Nature*: [Risks and benefits of dual-use research](#) (2005)<sup>4</sup>

- “It is important to develop clear guidelines about what research is considered sensitive, what is expected of researchers whose work produces dual-use outcomes, and how the government should in practice respond without losing the priceless virtue of open scientific scrutiny.”)

## **BIOSECURITY AND BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE, AND SCIENCE<sup>5</sup>**

Information for Contributors

### **CONSIDERATION OF INFORMATION THAT MIGHT INCREASE THE RISKS ASSOCIATE WITH POTENTIAL BIOWEAPON ATTACKS**

*Biosecurity and Bioterrorism* was created to foster discussion of biosecurity and bioterrorism issues and to promote informed biodefense decision making amongst policy makers, technical experts, and the public. However, the editors recognize that, in the process of promoting this critical debate, some of the articles published in this journal may contain information, such as public health biodefense preparedness vulnerabilities, biotechnologies, experimental methodologies, and medical response capacities, that could arguably lower the barriers to bioweapons attacks and/or increase the potential consequences of those attacks. There exists a recognized and important tension between academic freedom and the potential for

<sup>4</sup> [Risks and benefits of dual-use research](#). (2005) *Nature* 435(7044):855. Available online: <http://www.nature.com/nature/journal/v435/n7044/pdf/435855a.pdf>

<sup>5</sup> Available online: [http://www.liebertpub.com/manuscript.aspx?pub\\_id=111](http://www.liebertpub.com/manuscript.aspx?pub_id=111)

misapplication of scientific and other knowledge. Judgments must be made regarding the balancing of risks against the importance of an open, robust debate on these topics.

Given that essentially all biological science information is currently unclassified and available on the worldwide web and that medical and public health planning efforts are largely proceeding in the public domain, the editors believe that it will be a rare occasion that a decision not to publish potentially sensitive information will occur. While editorial procedures are in place to ensure such actions can occur should they be necessary, the editors have a strong commitment against withholding scientific or other information unless there are clear and compelling reasons to do so.

## ***SCIENCE***<sup>6</sup>

### General Information for Authors: Manuscript Selection

Some papers may need additional editorial oversight or present potential security concerns. Such papers will be brought to the attention of the Editor-in-Chief for further evaluation. If necessary, outside reviewers with expertise in the area will be consulted.

## ***PHYTOPATHOLOGY***<sup>7</sup> & ***THE COUNCIL OF THE AMERICAN PHYTOPATHOLOGY SOCIETY***<sup>8</sup>

### Guidelines for Electronic Manuscript Submission

APS Council has approved a biosecurity statement developed by the Publications Board to provide journal editors with a policy to screen potential articles for research that constitutes a misuse of plant pathological methods or a potential danger to society from the improper application of knowledge in our field. The full statement, which includes guidelines for authors, editors-in-chief, and senior editors of all APS journals, can be found at <http://www.apsnet.org/members/ppb/PDFs/BiosecurityAPSPubBoardPolicy.pdf>.

**Policy Guidelines of the Publications Board of The American Phytopathological Society in the Handling of Manuscripts Dealing With Crop Biosecurity and Agricultural Bioterrorism Issues** (Adapted with permission from the American Society of Microbiology <http://www.asmsusa.org>)

### ***Statement from APS Council***

“The Council of the American Phytopathological Society affirms the long-standing position of the Society that plant pathologists will work for the proper and beneficent application of science and will call to the attention of the public or the appropriate authorities, misuses of plant pathology or of information derived from plant pathology research. APS members are obligated to discourage any use of plant pathology contrary to the welfare of humankind, including the use of plant pathogens as biological weapons. Bioterrorism violates the fundamental principles expressed in the APS Code of Professional Conduct (<http://www.apsnet.org/members/gov/conduct.asp>) and is abhorrent to the APS and its members.”

<sup>6</sup> Available online: [http://www.sciencemag.org/about/authors/prep/gen\\_info.dtl#manuscript](http://www.sciencemag.org/about/authors/prep/gen_info.dtl#manuscript)

<sup>7</sup> Available online:

[http://apsjournals.apsnet.org/userimages/ContentEditor/1173286505152/phyto\\_author\\_instructions.pdf](http://apsjournals.apsnet.org/userimages/ContentEditor/1173286505152/phyto_author_instructions.pdf)

<sup>8</sup> Available online: <http://www.apsnet.org/members/ppb/PDFs/BiosecurityAPSPubBoardPolicy.pdf>

### ***APS Publications Board Policy and Procedures***

As described in the above Council resolution, the APS recognizes that there are valid concerns regarding the publication of information in scientific journals that could be put to inappropriate use. Members of the APS Publications Board will evaluate the rare manuscript that might raise such issues during the review process. Research articles must contain sufficient detail to permit the work to be repeated by others. By publishing in an APS journal, the authors agree that any fungi, bacteria, plasmids, viruses, and living materials, such as microbial strains and cell lines newly described in the article, are available from a national collection or will be made available in a timely fashion and at reasonable cost to members of the scientific community for non-commercial purposes. It is also expected that newly assigned GenBank/EMBL/DDBJ accession numbers for nucleotide and/or amino acid sequence data will be included in the original manuscript or be inserted when the manuscript is modified, and that the data will be released to the public by the time the manuscript is published. Supply of these materials must be in accordance with laws and regulations governing the shipment, transfer, possession, and use of biological materials and must be for legitimate, bona fide, research needs.

Please refer to the appropriate websites about these laws and regulations which can be found from the APS website (<http://www.apsnet.org/members/ppb/SelectAgentRegulations.asp>).

In order for the Publications Board to comply with the policy statement, ALL Editors of ALL APS journals should take the following course of action:

1. Ask ALL reviewers to advise the Senior Editor, by use of a confidential cover letter accompanying the review form, or an appropriate check-off box on the review form when
  - 1 Adapted with permission from the American Society for Microbiology (<http://www.asmsusa.org/>) it becomes available, if, in their opinion, the manuscript under review describes misuses of plant pathology or of information derived from plant pathology research.
2. The Senior Editor should serve as an initial screen with regard to this matter and may be the point of contact with the author(s).
3. If a reviewer brings such a matter to a Senior Editor's attention, the Senior Editor should provide copies of the manuscript to the Editor-in-Chief, the Chair of the Publications Board, and the APS Director of Publications. The Senior Editor should hold the manuscript and all reviews until contacted by the Editor-in-Chief.
4. The Editor-in-Chief will contact the Chair of the Publications Board, and together they may render a decision or, at their discretion, consult the entire Publications Board to determine whether to resume the review process or to decline the manuscript and return it to the author.

## Policy Statements on Dual Use Research

### ***WORLD ASSOCIATION OF MEDICAL EDITORS<sup>9</sup>***

#### WAME Policy Statements

#### **Geopolitical Intrusion on Editorial Decisions**

Decisions to edit and publish manuscripts submitted to the biomedical journals should be based on characteristics of the manuscripts themselves and how they relate to the journal's purpose and readers. Among these characteristics are importance of the topic, originality, scientific strength, clarity and completeness of written expression, and potential interest to readers. Editors should also take into account whether studies are ethical and whether their publication might cause harm to readers or to the public interest.

### ***JOURNAL EDITORS AND AUTHORS GROUP<sup>10</sup>***

#### **The statements**

**First:** The scientific information published in peer-reviewed research journals carries special status, and confers unique responsibilities on editors and authors. We must protect the integrity of the scientific process by publishing manuscripts of high quality, in sufficient detail to permit reproducibility. Without independent verification — a requirement for scientific progress — we can neither advance biomedical research nor provide the knowledge base for building strong biodefence systems.

**Second:** We recognize that the prospect of bioterrorism has raised legitimate concerns about the potential abuse of published information, but also recognize that research in the very same fields will be critical to society in meeting the challenges of defence. We are committed to dealing responsibly and effectively with safety and security issues that may be raised by papers submitted for publication, and to increasing our capacity to identify such issues as they arise.

**Third:** Scientists and their journals should consider the appropriate level and design of processes to accomplish effective review of papers that raise such security issues. Journals in disciplines that have attracted numbers of such papers have already devised procedures that might be employed as models in considering process design. Some of us represent some of those journals; others among us are committed to the timely implementation of such processes, about which we will notify our readers and authors.

**Fourth:** We recognize that on occasions an editor may conclude that the potential harm of publication outweighs the potential societal benefits. Under such circumstances, the paper should be modified, or not be published. Scientific information is also communicated by other means: seminars, meetings, electronic posting, etc. Journals and scientific societies can play an important role in encouraging investigators to communicate results of research in ways that maximize public benefits and minimize risks of misuse.

<sup>9</sup> Available online: <http://www.wame.org/resources/policies#geopolitical>

<sup>10</sup> Available online: <http://www.nature.com/nature/journal/v421/n6925/full/nature01479.html>, <http://www.pnas.org/cgi/content/full/100/4/1464>, <http://www.asm.org/media/index.asp?bid=20509>, <http://www.sciencemag.org/cgi/reprint/299/5610/1149.pdf>

***PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES*<sup>11</sup>**

Excerpt from Editorial by Nicholas R. Cozzarelli, Editor-in-Chief of *PNAS*

We must all recognize that protecting our world against both intentional acts of bioterrorism and the scourge of infectious diseases will depend on the effective communication of the science that we need for our common defense. At the same time, *PNAS* will continue to monitor submitted papers for material that may be deemed inappropriate and that could, if published, compromise the public welfare. We also urge authors to continue to act responsibly and to consider carefully the potential dual use of their results.

***NATIONAL ACADEMIES*<sup>12</sup>**

**Statement on Science and Security in an Age of Terrorism  
From Bruce Alberts, Wm. A. Wulf, and Harvey Fineberg,  
Presidents of the National Academies**

**October 18, 2002**

After the September 11, 2001, assaults on the World Trade Center and the Pentagon, and the subsequent anthrax attacks via the postal system, the scientific, engineering, and health research community was quick to respond at many levels, from initiating new research to analyzing needs for improved security. This community recognizes that it has a clear responsibility to protect the United States, as it has in the past, by harnessing the best science and technology to help counter terrorism and other national security threats.

In meeting this responsibility, the scientific, engineering, and health research community also recognizes a need to achieve an appropriate balance between scientific openness and restrictions on public information. Restrictions are clearly needed to safeguard strategic secrets; but openness also is needed to accelerate the progress of technical knowledge and enhance the nation's understanding of potential threats.

A successful balance between these two needs -- security and openness -- demands clarity in the distinctions between classified and unclassified research. We believe it to be essential that these distinctions not include poorly defined categories of "sensitive but unclassified" information that do not provide precise guidance on what information should be restricted from public access. Experience shows that vague criteria of this kind generate deep uncertainties among both scientists and officials responsible for enforcing regulations. The inevitable effect is to stifle scientific creativity and to weaken national security.

To develop sharp criteria for determining when to classify and/or restrict public access to scientific information, as well as to address the other important issues outlined below, we call for a renewed dialogue among scientists, engineers, health researchers and policy-makers. To stimulate such a dialogue, we present two "action points": one focused on scientists, engineers, and health researchers and the other focused on policy-makers.

Action Point 1

<sup>11</sup> Available online: <http://www.pnas.org/cgi/content/full/100/4/1463>

<sup>12</sup> Available online: <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=s10182002b>

The scientific, engineering, and health research community should work closely with the federal government to determine which research may be related to possible new security threats and to develop principles for researchers in each field. Among the questions that the scientific, engineering, and health community should address are the following:

Are there areas of currently unclassified research that should be classified in the new security environment?

How can the scientific, engineering, and health community establish systems that can monitor this issue effectively, as science and potential threats change over time?

Do any materials widely used in research require additional security procedures?

How can the scientific, engineering, and health community establish systems that will rapidly detect new potential threats from terrorism, as well as novel opportunities for countering terrorism, that arise from new discoveries, and convey these in an effective manner to the relevant government agencies?

### Action Point 2

The federal government should affirm and maintain the general principle of National Security Decision Directive 189, issued in 1985:

"No restrictions may be placed upon the conduct or reporting of federally funded fundamental research that has not received national security classification, except as provided in applicable U.S. statutes."

In determining what research and information should be restricted from public access, agencies should ask:

How should we apply the principle of building "high fences around narrow areas" in the new security environment, so as to protect critical and well-defined information and yet permit the essential flow of scientific and technical knowledge and human capital?

How can such determinations be made at the outset of a research program so as not to disrupt the research?

How can we avoid creation of vague and poorly defined categories of "sensitive but unclassified" information that do not provide precise guidance on what information should be restricted from public access?

How can the government enlist the help of a large number of the nation's best scientists, engineers, and health researchers in counterterrorism efforts, for both the unclassified and the classified areas of the overall program?

Achieving the purpose of scientific and technological activity -- to promote the welfare of society and to strengthen national security -- will require ingenuity from our science, engineering, and health community, as well as from the many agencies of the federal, state, and local governments involved in counterterrorism. The nation's safety and the continued improvement of our standard of living depend on careful, informed action on the part of both governments and the scientific, engineering, and health community. A continuing, meaningful dialogue needs to begin -- one that produces a true collaboration for the many decisions that need to be made.

BRUCE ALBERTS, President, National Academy of Sciences

WM. A. WULF, President, National Academy of Engineering

HARVEY V. FINEBERG, President, Institute of Medicine